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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/674,815	12/07/2000	Akira Aomatsu	5836-01-MJA	5030

7590 01/27/2005

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EXAMINER

KWON, BRIAN YONG S

ART UNIT	PAPER NUMBER
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1614

DATE MAILED: 01/27/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.		Applicant(s)	
	09/674,815		AOMATSU, AKIRA	
	Examiner		Art Unit	
	Brian S Kwon		1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 June 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 25-32 is/are pending in the application.
- 4a) Of the above claim(s) 32 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 25-31 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input checked="" type="checkbox"/> Other: <u>See Continuation Sheet</u> . |

Continuation of Attachment(s) 6). Other: Copy of Hyperdictionary (Webster's 1913 Dictionary).

DETAILED ACTION

RCE Application

1. Acknowledgment is made of applicant's filing of US Application No. 09/674815 as a Request For Continued Examination (RCE).
2. Claims 25-32 are currently pending in the application, however, claims 25-31 are being prosecuted on the merits of the case since the claim 32 is drawn to non-elected invention.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 25-27, 29 and 31 are rejected under 35 USC 102(b) as being anticipated by Woodruff (US 5084479).

The claims read on a composition comprising alpha-amino acid and a 4-amino-3-substituted-butanoic acid derivative selected from gabapentin, pregabalin, 3-aminomethyl-4-cyclohexyl-butanoic acid, 3-aminomethyl-5-cyclohexyl-pentanoic acid, 3-aminomethyl-4-phenyl-butanoic acid, and 3-aminomethyl-5-phenyl-pentanoic acid.

Woodruff discloses a solution comprising N-methyl-D-aspartic acid and gabapentin (column 8, line 5).

Since the claimed composition does not necessarily contain auxiliary agent (see definition of "optional" in attached Webster's 1913 Dictionary), the referenced composition

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anticipates the claimed composition. Furthermore, the claimed pharmaceutical dosage form refers to liquid, the referenced solution composition anticipates the claimed composition.

It is noted that recitations of inherent properties or characteristics are not limited to the interpretation of composition claim.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
 2. Ascertaining the differences between the prior art and the claims at issue.
 3. Resolving the level of ordinary skill in the pertinent art.
 4. Considering objective evidence present in the application indicating obviousness or nonobviousness.
4. Claims 25-31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Seiler et al. (Gen. Pharmac. Vol. 15, No. 4, pp. 367-369, 1984) and Costa et al. (US 5248678), and if necessary further in view of Liu et al. (European Journal of Pharmacology, 182, 1990, pp. 109-115).

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Seiler teaches or suggests the synergistic anticonvulsant effects of a GABA agonist and alpha-amino acid such as glycine. The reference discloses muscimol as the specific example of a GABA agonist.

Costa is being supplied as the reference to demonstrate the use of gabapentin, baclofen, vigabatrin and muscimol as GABA agonists.

Liu is being supplied as the reference to demonstrate the use of alpha-amino acid such as glycine in potentiating GABA agonist such as vigabatrin.

The teaching of Seiler differs from the claimed invention (i) in the combination use of gabapentin and glycine in a composition; (ii) the specific amount of alpha-amino acid (e.g., glycine) in said composition; (iii) the specific dosage formulation, for example liquid or solid preparation. To incorporate such teaching into the teaching of Seiler, would have been obvious in view of Costa who teaches or suggests the use of gabapentin as a GABA agonist.

One having ordinary skill in the art would have expected that gabapentin would have a similar property as muscimol due to its GABA agonist activity. One having ordinary skill in the art would have expected (as taught by Liu) that the addition of alpha-amino acid such as glycine to GABA agonists that are known in the art would potentiate activity of GABA agonist. Thus, one having ordinary skill in the art would have been motivated to make such modification such that the combination of gabapentin and glycine in a composition would provide synergistic anticonvulsant effect.

In addition, optimization of amounts of known active and/or inactive ingredients in a composition or determination of the specific delivery dosage form having optimum therapeutic index is well considered within the skill of the artisan, absent evidence to the contrary.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

5. Claims 25-31 are rejected under the judicially created doctrine of double patenting over claims 28-39 of Copending US Application No. 09/674,819.

Although the conflicting claims are not identical, they are not patentably distinct from each other because the scope of the claimed composition is overlapping with the claimed scope of the copending application. Since the interpretation of the instant claim allows for the inclusion of any other unspecified ingredients even in major amounts in said composition, the presence of humectant in said composition in the copending application makes obvious the instant claims.

Conclusion

6. No Claim is allowed.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian Kwon whose telephone number is (571) 272-0581. The examiner can normally be reached Tuesday through Friday from 9:00 am to 7:00pm.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low, can be reached on (571) 272-0951. The fax number for this Group is (703) 872-9306.

Any inquiry of a general nature of relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (571) 272-1600.

Brian Kwon

A handwritten signature in black ink, appearing to read 'Brian Kwon', with a long horizontal line extending to the right.

This is **G o o g l e**'s cache of <http://www.hyperdictionary.com/dictionary/optional> as retrieved on Dec 31, 2004 06:53:56 GMT.

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English Dictionary Computer Dictionary Thesaurus Dream Dictionary Medical Dictionary

Search Dictionary:

Meaning of OPTIONAL

Pronunciation: 'Œpshunl

WordNet Dictionary

Definition: [adj] possible but not necessary; left to personal choice

Websites: • **Find the Best Sites For Optional With Starware**

Starware search is an excellent resource for quality sites on Optional and much more! Starware also provides related listings for Optional.
search.starware.com

Synonyms: elective, ex gratia, facultative, nonmandatory, nonobligatory

Antonyms: obligatory

Webster's 1913 Dictionary

Definition: \Op"tion*al\, a.
Involving an option; depending on the exercise of an option; left to one's discretion or choice; not compulsory; as, **optional** studies; it is **optional** with you to go or stay. -- n. See {Elective}, n.

If to the former the movement was not **optional**, it was the same that the latter chose when it was **optional**.
--Palfrey.

Original writs are either **optional** or peremptory.
--Blackstone.

Thesaurus Terms

Related Terms: alternative, arbitrary, autonomous, discretionary, discretionary, disjunctive, elective, free, free will, gratuitous, independent, nonmandatory, offered, proffered, self-acting, self-active, self-determined, self-determining, spontaneous, unasked, unbesought, unbidden, uncalled-for, uncoerced, uncompelled, unforced, uninfluenced, uninvited, unpressured, unprompted, unrequested, unrequired, unsolicited, unsought, volitional, voluntary, volunteer, willful